



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Prospective Grant of an Exclusive Patent License: Virus-Like Particles Vaccines
Against Human Polyomaviruses, BK Virus (BKV) and JC Virus (JCV)**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to BioE Holdings Inc. (parent company, Biological E Ltd.) located in Los Altos, California.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Kevin W. Chang, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: changke@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 61/508,897 filed July 18, 2011 and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Reference No. E-168-2011-0-US-01]; PCT Patent Application No. PCT/US2012/047069 filed July 17, 2012, and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Reference No. E-168-2011-0-PCT-02]; Australian Patent No. 2012284122 issued September 14, 2017, and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Reference No. E-168-2011-0-AU-03]; Canadian Patent Application No. 2842180 filed July 17, 2012 and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Ref. No. E-168-2011-0-CA-04]; European Patent Application No. 12741191.6 filed July 17, 2012 and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Ref. No. E-168-2011-0-EP-05]; Japanese Patent No. 6030650 issued October 28, 2016 and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Ref. No. E-168-2011-0-JP-06]; United States Patent No. 9,764,022 issued September 19, 2017 and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Ref. No. E-168-2011-0-US-07]; United States Patent Application No. 15/694,567 filed September 1, 2017 and entitled, “Methods and Compositions for Inhibiting Polyomavirus-Associated Pathology” [HHS Ref. No. E-168-2011-0-US-08]; United States Provisional Patent Application No. 61/919,043 filed December 20, 2013

and entitled, “Immunogenic JC Polyomavirus Compositions and Methods of Use” [HHS Reference No. E-549-2013-0-US-01]; PCT Patent Application No. PCT/US2014/071621 filed December 19, 2014, and entitled, “Immunogenic JC Polyomavirus Compositions and Methods of Use” [HHS Reference No. E-549-2013-0-PCT-02]; United States Patent No. 9,931,393 issued April 3, 2018, and entitled, “Immunogenic JC Polyomavirus Compositions and Methods of Use” [HHS Reference No. E-549-2013-0-US-03]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: “Virus-Like Particle (VLP) BKV and JCV polyomavirus vaccine(s) for the prevention and/or treatment of BKV and/or JCV associated diseases in organ/kidney transplantation, bone marrow transplantation, and progressive multifocal leukoencephalopathy (PML).”

This technology discloses vaccine compositions and methods for eliciting immune responses to prevent or treat infections by two human polyomaviruses, BK virus (BKV) and JC virus (JCV), and their associated diseases using the vaccine compositions, which employ the capsid protein of certain serotypes of BKV and JCV as the immunogen. In particular, the vaccine is composed of virus-like particles that are formed from the capsid proteins of the viruses.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published

notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: January 31, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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